No. 121

In the Supreme Court of the United States

OCTOBER TERM, 1947

UNITED STATES OF AMERICA, PETITIONER

v.

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY

ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES

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OPINIONS BELOW

The opinion of the circuit court of appeals (R. 58–63) is reported at 161 F. 2d 629. The opinion of the district court (R. 11–27) is reported at 67 F. Supp. 192.

JURISDICTION

The judgment of the circuit court of appeals was entered May 12, 1947 (R. 63). The petition for a writ of certiorari was filed June 10, 1947, and was granted October 13, 1947. The jurisdiction of this Court is conferred by Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925. See also Rules 37 (b) (2) and 45 (a), F. R. Crim. P.

QUESTIONS PRESENTED

1. Section 301 (k) of the Federal Food, Drug, and Cosmetic Act prohibits the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to," a drug, if such an act is done while "such article is held for sale after shipment in interstate commerce and results in such article being misbranded." The question is whether this provision extends to a retail druggist who has purchased a drug shipped interstate from a wholesale source in the same state and who then misbrands the drug after it has reached his shelves.

2. If so, whether Section 301 (k) is a constitutional exercise of the commerce power.

STATUTE AND REGULATION INVOLVED

The Federal Food, Drug, and Cosmetic Act, June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, et seq.), provides in pertinent part:

> SEC. 301. The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. [21 U. S. C. 331 (a).]
>
> (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce. [21 U. S. C. 331 (b).]

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. [21 U. S. C. 331 (c).]

* * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded. [21 U. S. C. 331 (k).]

* * * * *

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine. [21 U. S. C. 333 (a).]

* * * * *

SEC. 502. A drug or device shall be deemed to be misbranded—

* * * * *

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. [21 U. S. C. 352 (c).]

* * * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement. [21 U. S. C. 352 (f).]

Regulation 2.106 (b) promulgated by the Acting Administrator on April 10, 1941, 6 Fed. Reg. 1920, provides:

(b) A shipment or other delivery of a drug or device shall be exempt from com-

pliance with the requirements of clause (1) of section 502 (f) of the Act if:

(1) Such shipment or delivery is made for use exclusively by or on the prescription of physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device;

(2) Adequate directions for so using such drug or device are available in scientific publications or otherwise;

(3) The label of such drug or device bears the statement "Caution: To be used only by or on the prescription of a ----------", or "Caution: To be used only by a ----------", the blank to be filled in by the word "Physician", "Dentist", or "Veterinarian", or any combination of two or all of such words, as the case may be;

(4) No representation appears in the labeling of such drug or device with respect to the conditions for which it is to be used; and

(5) In the case of a drug which is not designated solely by a name recognized in an official compendium and which is fabricated from two or more ingredients, its label also bears the quantity or proportion of each active ingredient.

Such exemption shall remain valid until all of such shipment or delivery is used by physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device, or is dispensed upon, and under labels bearing the directions for use specified in,

prescriptions of such physicians, dentists, or veterinarians. But if such shipment or delivery, or any part thereof, is otherwise disposed of as a drug or device, such exemption shall thereupon expire. The causing by any person of such an exemption so to expire shall be considered to be an act of misbranding for which such person shall be liable unless, prior to such disposition, such drug or device is relabeled to comply with clause (1) of section 502 (f) of the Act.

* * * * *

STATEMENT

On December 31, 1945, an information in two counts (R. 2–8) was filed in the United States District Court for the Middle District of Georgia charging respondent with violations of the Federal Food, Drug, and Cosmetic Act. Each count alleged that a bottle containing sulfathiazole tablets was shipped in interstate commerce from North Chicago, Illinois, to Atlanta, Georgia; that the bottle was then sold to respondent with the same label as when shipped in interstate commerce; that on a specified occasion, while respondent held the drug for sale in his drug store, he removed 12 tablets from the bottle, repacked them in a box bearing on the label only the name of the drug, and sold them; that the drug, as so repacked and sold, did not bear adequate directions for use as required by Section

502 (f) (1) of the Act and did not bear certain warnings required by Section 502 (f) (2) of the Act; and that the drug was thus misbranded, in violation of Section 301 (k) of the Act.[1]

On February 8, 1946, respondent filed a motion to dismiss the information (R. 10), in which he urged that no offense was charged; that his acts were not in interstate commerce and were thus beyond the power of Congress to regulate; that properly construed, Sections 301 (k) and 502 (f) (1) and (2) apply only to misbranding in interstate commerce; and that if Section 301 (k) were construed to apply to respondent's acts, it is unconstitutional and in violation of the Tenth Amendment. On June 19, 1946, the district court filed an opinion (R. 11–27) rejecting respondent's contentions.

Regulation 2.106 (b), under the Food, Drug and Cosmetic Act (*supra*, pp. 4–6) permits the shipment of various drugs in interstate commerce without appropriate instructions as to use if the drug is labeled with the prescription legend—"Caution: To be used only by or on the prescription of a physician"—and if various other specified conditions are satisfied. The regulation is designed to deal with those drugs for which adequate directions for lay use cannot be devised.

[1] Each count related to a separate transaction. The first count charged the respondent with causing the doing of the prohibited act. The second count alleged that respondent performed the act.

As we show below, it was pursuant to this regulation that the drug in this case was shipped in interstate commerce.

Respondent waived a jury trial (R. 28). The undisputed evidence at the trial showed that during the period between November 25, 1943, and March 15, 1944, Abbott Laboratories shipped to itself at Atlanta, Georgia, bottles containing 1,000 tablets of sulfathiazole and bearing a warning that the tablets were to be "used only by or on the prescription of a physician." (R. 29–30, 31, 34.)[2]

Respondent purchased one of these bottles in Atlanta, and it was shipped to him at Columbus,

[2] The label on the bottle which was shipped in interstate commerce and from which the 12 tablets were removed in each instance read as follows (see R. 3, 29):

"1,000 Tablets (Bisected)
"Sulfathiazole
"(Sulfanilamidothiazole)
"0.5 Gm. (7.7 grs.)
"Abbott
"List No. 3430

"CAUTION.—To be used only by or on the prescription of a physician.

"WARNING.—In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

"Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request.

"F5 Serial No. 311T237.

"Abbott Laboratories,
"North Chicago, Ill., U. S. A."

Georgia, where he operated a retail drug store (R. 29). On December 13, 1944, an inspector of the Food and Drug Administration purchased, without a doctor's prescription, 12 sulfathiazole tablets from respondent's drug store (R. 32). On the following day another inspector made a similar purchase (R. 38). In both instances, immediately prior to the sale, the tablets which were sold were removed from the container in which they were shipped and which bore the warning against their use without a physician's prescription; they were placed in small containers on which only the name of the drug—sulfathiazole—appeared (R. 29, 32, 35–37, 38).

Respondent was convicted on both counts (R. 49). The court suspended imposition of sentence and placed respondent on probation for two years on condition that he pay a fine of $200 (R. 50–51). Upon appeal to the Circuit Court of Appeals for the Fifth Circuit, the judgment was reversed on the ground that respondent's acts did not constitute a violation of Section 301 (k) of the Federal Food, Drug, and Cosmetic Act (R. 58–63). It was the view of the court that Section 301 (k) as applied in this case reaches only to the act of the importer of the interstate shipment and that it does not apply to a retailer who secures the drug intrastate from the importer.

SPECIFICATION OF ERRORS TO BE URGED

The circuit court of appeals erred:

1. In reversing the judgment of the district court.

2. In holding that the act of a retailer in removing a drug, which he held for sale after shipment in interstate commerce, from its properly labeled interstate container and placing it in another container without appropriate labeling is not a violation of Section 301 (k) of the Federal Food, Drug, and Cosmetic Act.

SUMMARY OF ARGUMENT

I

A. Section 301 (k) prohibits the misbranding of a product "while such article is held for sale after shipment in interstate commerce." Respondent's conduct clearly comes within these words. There is no basis in the statute for the action of the court below limiting the above language to the first sale after interstate commerce. Indeed, the court below recognized that the first clause of paragraph (k), which prohibits the "alteration, mutilation * * * or removal * * * of the labeling" could be applied to "anyone" who at any time destroys the interstate label (R. 60–61). But the same qualifying words, "held for sale after shipment in interstate commerce" necessarily mean the same thing when applied to the second clause of paragraph (k). The same words in the same paragraph cannot be accorded two different meanings.

The structure of Section 301 reflects an effort by Congress to protect the public, to the extent that it may constitutionally do so, at each stage of the movement of goods from their initial entry into the stream of commerce until they finally reach the consumer. Paragraphs (a), (b) and (c) prohibit the initial introduction into commerce of misbranded products, the misbranding of the product while it is in commerce, and the receipt in commerce and delivery of a misbranded product. If Congress had intended that paragraph (k) should apply only to the interstate importer, who is also reached by paragraph (c), apt words were available to accomplish this result. Significantly, the House Committee on Interstate and Foreign Commerce has recommended the addition to Section 301 (k), as a clarifying amendment to overcome the result of the decision below and conform to the original legislative intention, of the parenthetical phrase "whether or not the first sale."

B. There is nothing in the well-known purposes of the statute which justifies the confining construction of Section 301 (k) which the court below adopted. The Act on its face, as well as in its legislative history, demonstrates that its purpose is to protect *the consumer* against adulterated or misbranded foods, drugs and cosmetics which come through the channels of commerce. This Court has often so recognized. The committee report as to Section 301 (k) states that it

is intended "to extend the protection of consumers contemplated by law to the full extent constitutionally possible." H. Rep. No. 2139, 75th Cong., 3rd sess. This purpose will be substantially defeated if Section 301 (k) is subjected to the interpretation adopted by the court below. For under that decision the retailer can escape the federal regulation by arranging to purchase from an intra-state wholesaler or jobber, and by transferring articles to an improperly labeled container. Proper labeling is the only protection the consumer has from the serious dangers which likely will result from the use of drugs not in accordance with the cautionary warnings and directions required by the Act for the consumer's benefit.

II

The constitutional question which the court below sought to avoid (see R. 62) is whether Congress, to accomplish its primary purpose of protecting the consumer to the full extent of its constitutional power, may protect the interstate label or brand from misbranding after the article has reached the retailer and is held for sale by him. If, as we believe, protection of the label at the retail level is essential to the accomplishment of the objective of Congress in regulating the shipment of foods and drugs in commerce, the fact that Congress is regulating an intrastate act presents no constitutional obstacle. This Court

has sanctioned such regulation many times. See *Wickard* v. *Filburn,* 317 U. S. 111, 124; *United States* v. *Walsh,* 331 U. S. 432, 437. Only by the means which Congress has adopted can there be any assurance that the object of the regulation of the label in interstate commerce—consumer protection—will be achieved.

Section 301 (k) is a statutory embodiment of this Court's decision in *McDermott* v. *Wisconsin,* 228 U. S. 115, wherein the Court denied a state the right to require a local retailer to remove the interstate label on a product which he held for sale. The rationale of that decision demonstrates that to accomplish the statutory objective Congress must have the power to control the labeling until the article reaches the ultimate purchaser for whom the label is intended. In this respect, we perceive no constitutional difference between forbidding misbranding by removing the label, as in the *McDermott* case, and forbidding accomplishment of the same thing by removing the article from its properly labeled container and placing it in a mislabeled one, as in this case. Congress certainly must possess the power to prohibit the one as much as the other.

Section 301 (k) is not novel. Congress has in many other statutes legislated to protect the label under which a product moves in interstate commerce from misbranding while held for sale to the consumer. In the many years that such

statutory provisions have existed they have been challenged only once, and in that case the court explicitly held that Congress had the power to protect the interstate label while the product was held by a retailer for sale to the ultimate consumer. *United States* v. *Ury*, 106 F. 2d 28 (C. C. A. 2). This Court should be reluctant to overturn the repeated Congressional judgment that the means which it has adopted are essential to the accomplishment of its purpose.

ARGUMENT

INTRODUCTION

In *McDermott* v. *Wisconsin*, 228 U. S. 115, decided in 1913, this Court held that the Food and Drugs Act required the Federal label to be kept on products while they were held for sale on a retailer's shelves. Congress has since enacted a number of laws which have required the correct branding of products shipped in interstate and foreign commerce until they reached the ultimate consumer. The validity of these statutes has been challenged only once and then unsuccessfully.

The question here is not only whether Section 301 (k) of the Food, Drug, and Cosmetic Act of 1938 is valid but whether Congress has been incorrect in all of this legislation in assuming that it had power to protect the consumer against the misbranding of articles shipped across state lines

while they are held for sale at retail. Because of its doubts as to this constitutional issue, the court below construed Section 301 (k) as not reaching such acts by a retailer who is not the interstate importer—although the language, purpose, and history of the Section clearly forbade any such limited construction. It is the Government's position that the court below erred in not giving Section 301 (k) the construction required by its terms, and that the Section is constitutional if it is construed as Congress intended.

I

SECTION 301 (K) PROHIBITS THE MISBRANDING OF DRUGS WHILE THEY ARE HELD FOR SALE BY A RETAILER TO THE ULTIMATE CONSUMER

A. The language of the statute

Section 301 of the Food, Drug, and Cosmetic Act (52 Stat. 1042, 21 U. S. C. 331) provides:

> The following acts and the causing thereof are hereby prohibited:
>
> * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done *while such article is held for sale after shipment in interstate commerce*[3] and results in such article being misbranded.

[3] All italics used throughout the brief have been added.

It has not been, nor can it be, contended that the boxes of tablets sold by respondent were not misbranded under the Act and the regulations.[4]

The question raised by this case is whether Paragraph (k) extends to goods held by the retailer for sale to the ultimate consumer after shipment of the goods in interstate commerce to the wholesaler from whom the retailer purchased them. Respondent argued below that the Para-

[4] Section 502 (f) of the Act (52 Stat. 1051, 21 U. S. C. Sec. 352 (f)), declares that a drug shall be deemed to be misbranded "Unless its labeling bears (1) adequate directions for use", and permits the Administrator to promulgate regulations exempting drugs from this requirement when its observance "is not necessary for the protection of the public health". The Administration has issued regulations which exempt drugs from the requirement as to directions for use if and while they bear the "prescription legend" stating that they are to be used only by or on the prescription of a physician (or dentist, or veterinarian). See pp. 4–6, *supra*. The tablets sold by respondent were placed in a container which did not bear either the prescription legend or any directions for use, but merely the word "sulfathiozole." The label thus was clearly a misbranding within the meaning of Section 502 (f). The placement of the tablets in the misbranded boxes was equally clearly the "doing of any other act with respect to, a " * * * drug * * * [which] results in such article being misbranded", under Section 301 (k). Indeed, the trial court held that the acts of removing the tablets from a properly labeled container to the improperly labeled boxes "are in fact alteration or obliteration of part of the label" within the meaning of the first clause of Section 301 (k) (R. 24). The circuit court of appeals conceded that the portion of the drug placed in the boxes "became misbranded" (R. 60), and did not suggest that respondent's conduct would have been lawful if respondent had purchased the tablets directly from outside of the state.

graph should not be construed as extending to misbranding in intrastate commerce, but did not make any suggestion as to what the phrase italicized above could mean if the Paragraph were so limited. The court below held that the Paragraph applied "only to the holding for the first sale by the importer after interstate shipment" (R. 60), but then seemingly qualified its interpretation of "held for sale after shipment in interstate commerce" by observing that "the United States can prohibit the destruction of the labeling under which interstate commerce occurred, by anyone at any time, in order to preserve the evidence of what was done during the interstate movement" (R. 60–61). Although it is not clear, the inference from the opinion is that Paragraph (k) can properly be applied to such methods of tampering with the label even after the first sale.

The precise issue here is whether the clause "while such article is held for sale after shipment in interstate commerce" covers the conduct of respondent. Here the transactions occurred after shipment in interstate commerce and while the tablets were held for sale. There can be no question that they come within the plain and unequivocal language of the statute. The opinion below seems to concede this (R. 60). To interpret the clause as applying only to an act of misbranding by the original importer, while the goods were held for the *first sale* after interstate

shipment, is to read into the statute words which are not there.

Furthermore, the structure of Section 301 reflects an effort by Congress to protect the public, to the extent that it may constitutionally do so, at each stage of the movement of food and drugs from their initial entry into the stream of commerce until they finally reach the consumer. Section 301 (a) prohibits "the introduction or delivery for introduction into interstate commerce" of any misbranded or adulterated food, drug, device or cosmetic. The second stage is reached by Section 301 (b), which prohibits the misbranding, adulteration of any such item while "in interstate commerce." Section 301 (c) proscribes the "receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery of proffered delivery thereof for pay or otherwise."

Paragraph (c) carries the protection against misbranding of goods shipped interstate as far as the original importer by making it unlawful for him to receive and to deliver or offer to deliver such merchandise. Paragraph (k) then goes beyond Paragraph (c) to reach misbranding by anyone if an article is held for sale after interstate shipment. Clearly if Congress had meant to limit Paragraph (k) to the importer, more apt—and certainly less sweeping—words would have been chosen for that purpose.

That Section 301 (k) was not intended merely to reach the importer is confirmed by legislative events which have occurred since the decision below. During hearings on June 12, 1947, before a subcommittee of the House Committee on Interstate and Foreign Commerce on H. R. 3128 and H. R. 3147, with respect to a proposed amendment to Section 304 (a) of the Act, reference was made to the decision below in this case (pp. 7–9). The Committee thereupon recommended in its report (H. Rep. No. 807, 80th Cong., 1st Sess.) that Paragraph (k) be amended by insertion of the parenthetical phrase "whether or not the first sale" after the words "while such article is held for sale". The Report states specifically that—

> The insertion of the parenthetical wording "(whether or not the first sale)" in section 301 (k) is not designed to change the original intended meaning of the section but would simply make it entirely clear that "held for sale" includes the first sale and any subsequent sale. * * *[5]

[5] The Committee Report then continues: "As a result of a decision on May 12, 1947, by the Circuit Court of Appeals for the Fifth Circuit, in the case of *Jordan J. Sullivan* v. *United States*, doubts have arisen as to the ultimate judicial interpretation of the present language. Language similar to the present language occurs in other congressional enactments, such as the Federal Seed Act of 1912, as amended in 1926 (44 Stat. 325, 326; 7 U. S. C. 116 (b). (2)); the Federal Caustic Poison Act (44 Stat. 1406, 1408; 15 U. S. C. 404); and the Federal Alcohol Administration Act (49 Stat. 977, 983; 27 U. S. C. 205 (e)). The insertion of the parenthetical

The proposed amending bill is presently pending before the Congress. But this statement of the Committee responsible for food and drug legislation is a strong indication that the decision of the court below is not in accord with the original congressional intention. It is also to be noted that the same Committee approved an amendment to Section 507 of the Act (Act of March 10, 1947, Pub. L. No. 16, 80th Cong., 1st Sess.) so as to include streptomycin as well as penicillin upon the basis of a letter from the Federal Security Administrator which stated, *inter alia,* that under Section 301 (b) the drug would be protected while it was in interstate commerce and that under Section 301 (k) the protection would extend until the drug "was ultimately sold for use". See pp. 30–32, *infra.*

An additional reason for rejecting the construction of the statute adopted by the court below is the peculiar situation which acceptance of that interpretation would create. In the first place, it is to be noted that construing the paragraph as limited to the importer would not exempt all retailers, since a retailer who purchased directly from out-of-state sources would still be covered. But more significantly, the court below seems to concede that the first clause of Paragraph (k) which prohibits the "alteration, mutilation * * *

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clause by the amendments here under consideration is not intended to be taken as a reason for restricting the scope or meaning of these earlier enactments."

or removal * * * of the labeling" could be applied to "anyone" who "at any time" destroys the interstate label (R. 60–61). This concession was probably motivated by the fact that the court had no doubt as to the constitutionality of such an application of the Act under the *McDermott* case discussed *infra*, pp. 39–41. But the phrase "held for sale after shipment in interstate commerce" cannot have one meaning with respect to the offenses described in the first clause of Paragraph (k) and another with respect to those in the second clause. For the crucial words occur but once in the Paragraph and obviously mean the same thing as applied to each of the two clauses which precede them.

Furthermore, the district court found that the acts in question here constituted an "alteration or obliteration" of a label in violation of the first clause as well as "any other act" causing misbranding in violation of the second clause (R. 24). It would be anomalous to overturn this holding on the ground that Paragraph (k) reaches acts by any retailer which physically affect the interstate label, but only acts by the original importer if the same misbranding is accomplished by transferring the contents of a properly labeled container to an improperly labeled one. And yet that is what we believe the court below held.

B. The purpose of the statute

Nothing in the legislative history or well known purposes of the statute suggests that Section 301 (k) was not intended to mean what it says. On the contrary, they show that the Paragraph must be given a literal construction if the statute is to accomplish its objectives.

The purpose of the statute, as disclosed on its face as well as by its legislative history, is to protect *the consumer* against adulteration or misbranding of foods, drugs, and cosmetics, which come through the channels of interstate commerce. As this Court has noted, "The House Committee reported that the Act 'seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906.' (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation 'must not weaken the existing laws,' but on the contrary 'it must strengthen and extend that law's protection of the consumer.' (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1.)" *United States* v. *Dotterweich,* 320 U. S. 277, at 282. The House Report also declared that "the old law * * * is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions". And with respect to labeling, the Report explicitly stated that "Informative

labeling of foods as to quality and composition is required for the information and guidance of consumers".

In this setting, and in the light of these objectives, Paragraph (k)[6] was added to Section 301 by the House Committee. In explanation the Committee Report stated:

> * * * In general this section denies the channels of interstate commerce to products which are adulterated or misbranded or are otherwise unsafe for use. It order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment.

That the protection of consumers is the objective of the statute also appears from Section 401 (21 U. S. C. 341), dealing with food, and Section 502 (c) (21 U. S. C. 352 (c)), which relates to drugs. The former twice defines the criterion which is to guide the Administrator in establishing definitions and standards for food as the promotion of "honesty and fair dealing *in the interest of consumers.*" With respect to drugs,

[6] The subsection was inserted in the bill while it was pending before the committee, and so far as we know the quoted language is the only specific reference to the provision in the legislative history of the Act.

Section 502 (c) makes the test of proper branding whether information placed on the label is

> prominently placed thereon with such conspicuousness * * * and in such terms as to render it likely to be read and understood *by the ordinary individual under customary conditions of purchase and use.*

In many decisions this Court and other federal courts have also recognized that consumer protection is the ultimate statutory goal. In *McDermott* v. *Wisconsin,* 228 U. S. 115, the Court observed that this object would be defeated if the lawful label were not placed on the container which actually reached the consumer; the opinion states in this connection (pp. 130–131):

> * * * Within the limitations of its right to regulate interstate commerce, Congress manifestly is aiming at the contents of the package as it shall reach the consumer, for whose protection the act was primarily passed, and it is the branding upon the package which contains the article intended for consumption itself which is the subject-matter of regulation. Limiting the requirements of the act as to adulteration and misbranding simply to the outside wrapping or box containing the packages intended to be purchased by the consumer, so that the importer, by removing and destroying such covering, could prevent the operation of the law on the

> imported article yet unsold, would render the act nugatory and its provisions wholly inadequate to accomplish the purposes for which it was passed.
>
> The object of the statute is to prevent the misuse of the facilities of interstate commerce in conveying to and placing before the consumer misbranded and adulterated articles of medicine or food, and in order that its protection may be afforded to those who are intended to receive its benefits the brands regulated must be upon the packages intended to reach the purchaser. * * *

The same theme recurs in subsequent decisions. "The purpose of the act is to secure the purity of food and drugs and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it." *United States* v. *Antikamnia Co.*, 231 U. S. 654, at 665. "The legislation, as against misbranding, intended to make it possible that *the consumer should know* that an article purchased was what it purported to be * * *." *United States* v. *Lexington Mill Co.*, 232 U. S. 399, at 409. "* * * the legislative history of the statute manifests the purpose of Congress to substitute, for informative labeling, standards of identity of a food, sold under a common or usual name, so as to give *to consumers who purchase it under that name assurance* that they will get what they

may reasonably except to receive. * * *" *Federal Security Adm'r.* v. *Quaker Oats Co.*, 318 U. S. 218, at 232. "Here, *the consumer* would be unaware that less expensive ingredients had been substituted and that the article was inferior to that which he expected to receive when making his purchase. The fact that the substituted article was not deleterious is immaterial. From its inception, to its last amendment, the Pure Food and Drugs Act was * * * intended to protect the consuming public." *United States* v. *Two Bags, Etc.*, 147 F. 2d 123, at 127 (C. C. A. 96). "* * * it is manifest that misbranding has true significance only in terms of *the consumer* * * *." *United States* v. *7 Jugs, Etc. of Dr. Salsbury's Rakos*, 53 F. Supp. 746, at 754 (D. Minn.).

There can thus be no question that the purpose of the Act, and of Section 301 (k), in particular, is, in the language of the Committee Report "to extend the protection of consumers contemplated by the law to the full extent constitutionally possible."

This purpose will be, to a considerable extent, defeated if Section 301 (k) is subjected to the confining construction placed upon it by the court below. For although the statutory scheme is directed at the use of accurate labeling which "the ordinary individual under customary conditions of purchase and use" can "read and" under-

stand (Section 502 (c), 21 U. S. C. 352 (c)), such a limiting construction of the statute would mean that the protection of the law disappeared before the product reached the person for whom the accurate labeling was intended.

Under the decision below, goods held for sale to ultimate consumers by retailers who purchase the articles directly from outside the state would be covered. But undoubtedly a large proportion of food, drugs and cosmetics is purchased by retailers from wholesalers within the same state.[1] And any retailer who is disposed not to comply with the statute could see to it that he obtained his supplies from wholesalers in his state, whether he otherwise would have done so or not.

The same situation would prevail as to that portion of the opinion below which indicates that, on the one hand, retailers can not lawfully alter the actual labels which have arrived through the channels of interstate commerce, but that they can with impunity remove the articles to an improperly labeled container. Retailers who are disposed not to label their products accurately, or to sell dangerous drugs without a prescription—and it is only against such retailers that

[1] Only about 20% of the drugs manufactured are sold directly by the manufacturer to the retailer, while more than two-thirds are sold first to wholesalers or jobbers. The remainder are sold directly to professional or industrial users or are exported. See 5 Census of Business, 1939, table 1, p. 95; 2 Standard and Poor's Trade and Securities, p. D 1–4.

the public needs to be protected—would find that the opinion below created a wide loophole in the statutory scheme.

The injury to the public health which may result if the protection of the statute is lifted before the articles reach the ultimate consumer is particularly serious insofar as drugs are concerned. Many drugs which are extremely useful in curing disease are also extremely dangerous. Such drugs include the sulfonamides, which are powerful chemo-therapeutic agents; the barbiturates, which have hypnotic properties; thyroid, which may increase the metabolic rate; streptomycin, a new anti-biotic drug; digitalis, which has a profound effect on heart action; thiouracil, which is useful in the treatment of hyperthyroidism but which has the ability to destroy the body's capacity to produce white blood cells; benzedrine, a stimulant for the central nervous system which when used unwisely is followed by total collapse; insulin, for the treatment of diabetes but which causes severe shock when used in overdosage; thiocyanates, which are useful in treating hypertension but may result in vascular collapse; and curare, which causes relaxation of the muscles but may result in total paralysis and death.

While Congress undoubtedly did not intend to exclude such drugs from interstate commerce, it did mean to condition their interstate movement on compliance with regulations which would safeguard the public health.

Section 502 (f) and the regulations promulgated thereunder (see pp. 4–6, *supra*) provide that a drug shall be deemed misbranded "Unless its labeling bears (1) adequate directions for use", or, in the alternative, the prescription legend stating that the drug is to be used only on the prescription of a physician.[8] If these provisions do not extend to the product while it is held for sale at retail, unscrupulous druggists can deprive the public of the protection which the Act was designed to establish for all drugs which have moved in interstate commerce.

This case itself affords an excellent illustration. It involves sulfathiazole, a drug which is well known to have profound physiological effects even when used under a physician's care. The dangers to the public health which will result if such a drug can be sold indiscriminately without adequate directions are obvious.[9] Here the lawful

[8] As to the drugs referred to above, directions adequate for use by the layman could hardly be devised; their safe and efficacious use requires the supervision of a physician.

[9] Medical literature dealing with the serious complications which may result from the use of the drug abundantly illustrates this fact. See e. g., Garvin, "Complications Following the Administration of Sulfanilamide," 113 Journ. American Medical Association 228–291 (1939); Corr and Root, "Death From Granulocytopenia After Sulfanilamide Therapy," 112 Journ. American Medical Association 1939–1940 (1939); Reinhold, Flippin and Schwartz, "Observations On The Pharmacology And Toxicology Of Sulfathiazole In Man," 199 American Journal of The Medical Sciences 393–401 (1940); Bigler and Haralamibie' "Sulfanilamide And Related Compounds," 57 American Journal of Diseases of Children 1110, 1119–1128 (1939).

label placed upon the jar containing the tablets by the manufacturer stated not only that the tablets were to be used only on the prescription of a physician, but also included a warning (R. 3, 29) that

> In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

When respondent sold the tablets both the prescription legend and the warning were deleted.

There are other instances wherein the public health would be jeopardized by a denial of the full sweep of Section 301 (k). Drugs containing insulin, penicillin, or streptomycin cannot legally move in interstate commerce unless, pursuant to regulations promulgated by the Administrator under Sections 506 and 507,[10] they are pretested and certified by the Food and Drug Administration. The plan of control of these drugs is designed to insure their safety and efficacy in the treatment of numerous diseases. Among other things the statute requires that the labeling of a certified batch must bear an expiration date beyond which the drug is deemed not to be fully

[10] These sections were added to the statute in 1941 and 1945. See 55 Stat. 851, 59 Stat. 463, 21 U. S. C. Supp. V, 352 (k) (l) 356, 357.

potent."[11] It had been assumed by the Federal Security Agency, justifiably we believe, that any dealer, including retail druggists, who did any act with respect to such a drug which would falsify or remove this expiration date was subject to prosecution under Section 301 (k). In a letter to

[11] H. Rep. 1542, 77th Cong., 1st sess., accompanying H. R. 6251 which became Section 506, contained the following statement from the Committee on Interstate and Foreign Commerce: "Each user of insulin must learn through his physician the quantity and frequency of dosage necessary for him. Most diabetics subsequently buy their insulin direct from drug stores and administer it to themselves with only occasional checkups by physicians. If the drug is too strong, insulin convulsions may follow and even death. If it is too weak, coma may result from which the patient may not recover. Such results are particularly likely if he is relying upon himself alone for the administration of the drug. With no other drug are the consequences of failure of accurate standardization so dramatic and so immediate.

* * * * *

"* * * Inasmuch as over-age or improperly packaged or labeled insulin is unsafe, such certificates are to be effective only for periods prescribed in the regulations, and the certified batches and drugs therefrom are to be protected by such certificate only for the prescribed period, or for such part thereof as such drug meets the labeling and other requirements prescribed in such regulations for the protection of the public."

See also S. Rep. 410, 79th Cong., 1st sess., accompanying H. R. 3266; and S. Rep. 45, 80th Cong., 1st sess., accompanying S. 445, which became the penicillin and streptomycin amendments to the Act. The reports emphasize the importance, in terms of the public health, of preventing the distribution to consumers of these drugs after the expiration date of effective certificates or in containers that do not bear the required labeling.

the Speaker of the House of Representatives[12] dated January 22, 1947 (see H. Rep. No. 75, 80th Cong., 1st sess.) recommending passage of the Act of March 10, 1947, Pub. L. No. 16, 80th Cong., 1st sess., so as to include streptomycin as well as penicillin, the Federal Security Administrator said:

> The extreme rarity with which uncertified insulin or penicillin is introduced into interstate commerce demonstrates that the certification procedure substantially insures that drugs subject to it are what they ought to be when their interstate movement begins. The provision of the act in section 301 (b), which prohibits the adulteration or misbranding of an article while in interstate commerce, tends to safeguard the product during that time. Likewise, the provision of the act in section 301 (k), prohibiting the doing of any act with respect to an article while it is being held for sale after interstate shipment if such act results in the misbranding of the article, tends to extend protection until it is ultimately sold for use. (It will be noted that uncertified insulin and penicillin are defined in section 502 (k) and (l) as misbranded.)

It was in large part upon the basis of the explanation contained in this letter that Congress passed the streptomycin amendment (see H. Rep.

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[12] A similar letter was sent to the Chairman, Committee on Interstate and Foreign Commerce on February 25, 1947 (S. Rep. No. 45, 80th Cong., 1st sess.).

No. 75, 80th Cong., 1st sess.; S. Rep. No. 45, 80th Cong., 1st sess.).

We think it clear that the public health which the statute seeks to protect would be imperiled if the statutory provision against misbranding of drugs became inoperative before the goods shipped in interstate commerce were sold to the ultimate consumer. Accordingly, we submit that the purpose as well as the language of Section 301 (k) requires that it be construed so as to reach misbranding occurring at that stage of the distribution process.

It is apparent from the opinion below that the circuit court of appeals would not have given to the statute a narrower construction if it had not thought that a literal interpretation would have been unconstitutional. In Point II we shall show that Section 301 (k) would not be invalid if it is interpreted in the manner which its words, history and purpose all combine to require.

II

THE UNDISPUTED POWER OF CONGRESS TO REQUIRE A PROPER LABEL ON A DRUG WHICH MOVES IN INTERSTATE COMMERCE EXTENDS TO THE PROTECTION OF THAT LABEL UNTIL THE PRODUCT REACHES THE ULTIMATE CONSUMER. THIS IS AN APPROPRIATE MEANS FOR ACHIEVING THE OBJECTIVE OF CONGRESS IN REQUIRING THAT DRUGS BE PROPERLY LABELED

The constitutional question which the circuit court of appeals sought to avoid (see R. 62) is whether Congress, to accomplish its primary purpose of protecting the consumer to the full extent of its constitutional power, may protect the label

or brand by which a product moves in interstate commerce from misbranding after the article has reached the retailer and is held for sale by him. In other words, may Congress in the exercise of the commerce power confer on the consumer the right to know that the drug which he purchases from the local drug store moved in interstate commerce labeled with specified warnings and directions for use; or that the canned food which he purchases in the local grocery store moved in interstate commerce as standard or substandard merchandise;[13] or that the meat product which he purchases passed federal inspection; or that the clothing which he purchases was manufactured from material containing only a specified amount of virgin wool; or that the imported article which he purchases from a local store was produced in a specified country.

The test in determining the validity of Section 301 (k) is, of course, not whether the drugs are still in interstate commerce at the time the federal statute is sought to be applied. This Court has frequently held that intrastate transactions can be regulated under the Commerce Clause, and that it is immaterial whether such acts are part of "production" or "consumption" or "marketing" or of a "local character". *Wickard* v. *Filburn*, 317 U. S. 111, 124. The intrastate

[13] See, e. g., Definitions and Standards of Quality for Canned Green Beans and Canned Wax Beans, promulgated February 19, 1947, 12 Fed. Reg. 1137, 1140–1141.

operations of the Chicago milk dealer in *United States* v. *Wrightwood Dairy*, 315 U. S. 110, who bought and sold his milk intrastate though in competition with interstate milk, and the feeding of wheat on a farm by the appellee in *Wickard* v. *Filburn*, obviously were "local" transactions. *McDermott* v. *Wisconsin*, 228 U. S. 115, discussed, *infra*, pp. 39–42, and many cases under the National Labor Relations Act [14] indicate that there is nothing novel in subjecting transactions of retailers after commerce has ceased to the federal regulatory power, if such regulation is reasonably necessary to effectuate the objective of Congress in regulating interstate commerce.

As this Court stated in *United States* v. *Wrightwood Dairy*, 315 U. S., at 119, *Wickard* v. *Filburn*, 317 U. S., at 124, and *United States* v. *Darby*, 312 U. S. 100, 118–122:

> The commerce power is not confined in its exercise to the regulation of commerce among the states. It extends to those activities intrastate which so affect inter-

[14] *Labor Board* v. *Kudile*, 130 F. 2d 615 (C. C. A. 3), certiorari denied, 317 U. S. 694; *Labor Board* v. *J. L. Hudson Co.*, 135 F. 2d 380 (C. C. A. 6), certiorari denied, 320 U. S. 740; *J. L. Brandeis & Sons* v. *Labor Board*, 142 F. 2d 977 (C. C. A. 8), certiorari denied, 323 U. S. 751; *Labor Board* v. *M. E. Blatt Co.*, 143 F. 2d 268 (C. C. A. 3), certiorari denied, 323 U. S. 774; *Labor Board* v. *Suburban Lumber Co.*, 121 F. 2d 829 (C. C. A. 3), certiorari denied, 314 U. S. 693; *Loveman, Joseph & Loeb* v. *Labor Board*, 146 F. 2d 769 (C. C. A. 5); *Labor Board* v. *Richter's Bakery*, 140 F. 2d 870 (C. C. A. 5), certiorari denied, 322 U. S. 754.

> state commerce, or the exertion of the power of Congress over it, as to make regulation of them appropriate means to the attainment of a legitimate end, the effective execution of the granted power to regulate interstate commerce. * * * The power of Congress over interstate commerce is plenary and complete in itself, may be exercised to its utmost extent, and acknowledges no limitations other than are prescribed in the Constitution. * * *

And the *Wickard* and *Darby* cases also illustrate and hold that the commerce power may apply to individual intrastate acts which, in isolation, only have a trivial effect when the totality of similar transactions would have a substantial effect upon the regulation of commerce. See also *National Labor Relations Board* v. *Fainblatt*, 306 U. S. 601.

The Court has recently applied this test in upholding the application to intrastate transactions of the Food, Drug and Cosmetic Act itself; in *United States* v. *Walsh*, 331 U. S. 432, 437, the Court stated:

> The commerce clause of the Constitution is not to be interpreted so as to deny to Congress the power to make effective its regulation of interstate commerce.

We think that Section 301 (k) fully satisfies these tests. As we have shown, pp. 22–26, *supra*, in the Food, Drug, and Cosmetic Act Congress has

exercised its commerce power to control the labeling of products moving in interstate commerce in order to protect the ultimate consumer. No one questions that this statute and its objective are legitimate exertions of the federal power under the Commerce Clause. To provide that the labeling required for interstate shipment remain on the product until it is sold to the consumer is clearly an "appropriate means to the attainment of [this] legitimate end." For it is only by this means that there can be any assurance that the object of the regulation of the label in interstate commerce—consumer protection—will be achieved.

Under this statute a retailer who wishes to sell goods which come through the channels of interstate commerce must take them subject to the conditions as to accurate branding that Congress has imposed. He is not under compulsion to sell products which come from other states. If he chooses to do so, he must accept both the benefits of the Federal regulation which guarantees the accuracy of the branding of the goods which he receives and the obligation not to misbrand the products so received until they reach the consumer whom the regulation is designed to protect.

Furthermore, the court below did not doubt the power of Congress to reach articles held for sale by a retailer who receives them directly from an extrastate supplier, or to prevent destruction of the interstate label by any retailer holding the

articles for sale. This exercise of the commerce power would be readily subject to evasion, as we have seen, if retailers could avoid having to comply with the statute by arranging to purchase through an intrastate intermediary, or by transferring the article to another container instead of destroying the original label. Congress may provide for the "effective execution" of the granted power by closing these avenues of escape.

In the recent Committee report recommending a clarifying amendment to Section 301 (k) to overcome the decision below in the instant case (see pp. 19–20, *supra*), the House Committee on Interstate and Foreign Commerce stated (H. Rep. 807, 80th Cong., 1st sess., pp. 5–6):

> The Federal Food, Drug, and Cosmetic Act was passed to protect the health and pocketbook of the consuming public. Carefully drawn definitions of a wide variety of adulterations, misbrandings, and other offenses with respect to foods, drugs, devices, and cosmetics are set up by the act, and the channels of commerce are forbidden to the offending articles. In order to prevent the frustration and defeat of its purpose, Congress must exercise its power to continue that protection against articles that become filthy, decomposed, deteriorated, or otherwise adulterated or misbranded while awaiting sale to the ultimate consumer. Otherwise the safeguards which were designed to maintain the integrity of the products to the end of their interstate jour-

> ney become futile and the purpose of the regulation becomes sterile and fails of fruition.

These principles were applied by the Court under the original Food and Drugs Act almost thirty-five years ago in *McDermott v. Wisconsin*, 228 U. S. 115. We submit that Section 301 (k) is a statutory embodiment of that decision.

McDermott, a retail grocer in Wisconsin, purchased canned corn syrup in Illinois, the cans being shipped in wooden boxes. The labels on the cans conformed to the requirements of the Federal Food and Drugs Act. McDermott unpacked the containers in which the articles were shipped and placed the individual cans on his shelves for sale at retail. He left on the cans the labels which were on them during the course of their interstate journey. A Wisconsin statute would have required McDermott to remove the labels then on the cans and to place on them new labels which described the contents of the cans in different terms. McDermott was convicted in the State courts for failing to comply with the State law, and he brought the case to this Court, contending "that the Federal Food and Drugs Act passed under the authority of the Constitution has taken possession of this field of regulation and that the state act is a wrongful interference with the exclusive power of Congress over interstate commerce * * *." 228 U. S., at 127.

This Court reversed the conviction, and held the relevant provisions of the State law invalid

because they interfered with the operation of the Federal statute. The opinion of the Court stated (228 U. S. at 128):

> The Food and Drugs Act was passed by Congress, under its authority to exclude from interstate commerce impure and adulterated food and drugs and to prevent the facilities of such commerce being used to enable such articles to be transported throughout the country from their place of manufacture *to the people who consume and use them,* and it is in the light of the purpose and of the power exerted in its passage by Congress that this act must be considered and construed. *Hipolite Egg Co.* v. *United States* [220 U. S. 45].

The opinion pointed out, in the passage quoted at pages 24–25, *supra,* that to limit the protection under the statute to the box in which the goods were shipped in commerce, as distinct from the package to be purchased "by the consumer * * * would render the act nugatory and its provisions wholly inadequate to accomplish the purposes for which it was passed" (228 U. S. at 130–131). The Court held that the statute must be construed to require the correct brand on the package intended to reach the purchaser, and that, so construed, the requirements of the act were "clearly within the powers of Congress over the facilities of interstate commerce" (228 U. S. at 131). In answer to the argument that the commerce power extended only to the original package in which the goods were shipped inter-

state, the Court also stressed the importance, from the standpoint of enforcement of the regulation of the label carried in interstate commerce, of retaining the original label on the goods until they were sold (228 U. S., at 136).

Section 301 (k) specifically added to the present Act what this Court read into the misbranding provisions of the predecessor statute in the *McDermott* case. And the rationale of the *McDermott* decision in large measure demonstrates the constitutional basis for the provision. The *McDermott* decision recognized both that protection of the interstate label while the product is held for sale by the local dealer is an important enforcement device, and that to accomplish the statutory objective of protecting the consumer, Congress must have the power to control the labeling until the article reaches the ultimate purchaser for whom the label is intended.

The *McDermott* case, it is true, involved a retailer who purchased the products directly from outside the state. But nothing in the opinion or its reasoning turns on that fact, or suggests that the result would have differed if the goods had been received from an intermediary who had brought them into the state. When the goods were placed on the retailer's shelf for general sale, they were no longer in interstate commerce irrespective of whether they were purchased directly from outside the state or not. Cf. *Walling* v. *Jacksonville Paper Co.*, 317 U. S. 564.

There was thus the same need of showing a relationship between an intrastate transaction and the effective regulation of interstate commerce.

The court below sought to distinguish the *McDermott* case on the ground that although Congress may forbid the retailer to alter or destroy the interstate label and thus misbrand the article, it perhaps may not reach a situation in which the original physical label is not affected. But the difference between denying the retailer the right to destroy the label and denying him the right to accomplish the same thing by removing the article from its properly labeled container and placing it in a misbranded one is certainly not of constitutional stature. Either method of changing the label accomplishes the same result—frustration of the congressional objective to protect the consumer from misbranding. Congress certainly must possess the power to prohibit the one as much as the other.

The act here involved is not the only statute in which Congress has required that the labels prescribed for interstate or foreign commerce must remain on the goods until the ultimate sale. Thus Section 5 of the Wool Products Labeling Act of 1940 (54 Stat. 1128, 15 U. S. C. 68 c) requires any person manufacturing or first introducing into commerce a wool product to affix to it a label describing the content of the product, and

further provides that the label shall remain affixed to the product "until sold to the consumer."[15] Criminal penalties are provided for any person who with intent to violate the act alters or removes such a label (Secs. 5, 10, 15 U. S. C. 68c and 68h).

Section 6 of the Federal Caustic Poison Act of 1927 (44 Stat. 1406, 15 U. S. C. 406) prohibits the alteration, mutilation, etc., of any label on such a substance which is being "Shipped in interstate * * * commerce" or "Held for sale or exchange after having been so shipped." Section 5 (e) of the Federal Alcohol Administration Act of 1935 (49 Stat. 983, 27 U. S. C. 205 (e)) makes it unlawful to alter, destroy or remove any brand or label "upon distilled spirits * * * held for sale in interstate or foreign commerce or *after shipment therein*" except as authorized by federal law or administrative regulation. Section 6 (b) of the Importation of Adulterated Seeds Act, as amended by the Act of April 6, 1926, 44 Stat. 325, 326, provided, *inter alia,* for the condemnation of any misbranded seed which was "Held for sale or

[15] The Act provides for the use of substitute labels whenever a person subject to the act finds that the label affixed to the article does not comply with the act (Sec. 4 (c), 15 U. S. C. 68 b (c)), and it contemplates that where the wool product does not remain in the original state in which it is first labeled, as, for example, when wool material is made into a suit, that a substitute label shall be placed on the finished product (Sec. 5, 15 U. S. C. 68 c).

exchange after having been" transported in interstate commerce.[16] Section 304 of the Tariff Act of 1930 (19 U. S. C. 1304) requires that every article imported into the United States and its container and package be conspicuously marked or labeled in English to indicate the country of origin, and makes it an offense to remove or deface any such mark with intent to conceal the information given by it. See also, Meat Inspection Act of 1907, 34 Stat. 1263 (21 U. S. C. 79).

Except for a single case arising under the section of the Tariff Act just referred to, there has never even been a challenge to the provisions in these statutes extending congressional protection of the interstate label to the ultimate consumer.[17] That case, however, is very closely in point.

In *United States* v. *Ury*, 106 F. 2d 28 (C. C. A. 2), the defendant appears to have been a local retailer in automobile parts who removed the word "Germany" from a number of generators which had been imported from that country. The court construed Section 304 as "including a de-

[16] The provision has been superseded by section 404 of the Federal Seed Act, 53 Stat. 1286 (7 U. S. C. 1594) which, similarly to section 304 of the Tariff Act, provides that "No person shall detach, alter, deface, or destroy any label * * *, or alter or substitute seed in any manner" that would defeat the purpose of the Act.

[17] Another decision applying the tariff provision to the acts of retailers is *Didia* v. *United States*, 106 F. 2d 918 (C. C. A. 9).

facing or removal after the goods have come to rest in a state," and as "certainly" proscribing the removal of the mark or label while the article was held on the retailer's shelf for sale. The court rejected the argument that the provision so construed was unconstitutional, for reasons which are equally applicable here, saying (106 F. 2d, at 29):

> It is said that the provision goes too far, that it represents an effort to regulate the goods after they have ceased to be subject to federal control. If the provision stood alone, there would be force in the argument. But this enactment is not the equivalent of a statute requiring local retailers to place a mark of origin on all imported goods, goods previously unmarked. It merely commands that a mark already on them by force of a valid federal enactment shall not be disturbed. The provision is one reasonably calculated to render effective the principal requirement that the goods bear a mark at the time of importation. If the marks required on imported goods might later be defaced with impunity, the marking requirement would be evaded and the fair operation of the law defeated. Congress, having exercised its undoubted power to require marks at importation, had also the incidental power to forbid the defacing of the mark at any time after importation. * * *

It thus appears that the method adopted in the Food, Drug and Cosmetic Act for insuring that the correct interstate labeling reaches the ultimate consumer is neither novel nor unique. It has been embodied in other statutes whose validity either has been assumed or upheld. We submit that this Court should be reluctant to overturn the repeated congressional judgment that protecting the interstate label until it reaches the ultimate consumer for whom alone it is meant is a proper exercise of the commerce power.

This Court has frequently recognized that Congress possesses the "choice of means" for the accomplishment of the powers granted to it (*McCulloch* v. *Maryland*, 4 Wheat. 316, 409–421; *United States* v. *Fisher*, 2 Cranch 358, 396; *Legal Tender Case*, 110 U. S. 420, 440; *Everard's Breweries* v. *Day*, 265 U. S. 545, 560; *First National Bank* v. *Union Trust Co.*, 244 U. S. 416, 419). The principle has often been applied in cases involving the regulation of intrastate transactions under the Commerce Clause. *Stafford* v. *Wallace*, 258 U. S. 495, 521; *Chicago Board of Trade* v. *Olsen*, 262 U. S. 1, 37; *United States* v. *Darby*, 312 U. S. 100, 121–122; *Virginian Ry. Co.* v. *System Federation*, 300 U. S. 515, 553; *Wickard* v. *Filburn*, 317 U. S. 111, 128–129. Cf. *United States* v. *Carolene Products Co.*, 304 U. S. 144, 152. Congress has shown quite plainly in respect of the present statute, as well as in the similar provisions to which we have referred, that it

regards protection of the interstate label as a necessary means for accomplishing its purpose.

It is no answer to suggest, as the court below does (R. 61), that the laws of the state in which respondent does business are adequate to complement the federal food and drug legislation and thus to protect the consumer from the evils at which the federal legislation is directed. It is for Congress to determine the national policy over interstate commerce, irrespective of state law, and the congressional enactment is no less valid because some of the states may have acted to meet the same evil. Cf. *United States* v. *Darby*, 312 U. S. at 114. Furthermore, only about 13 of the 48 states have laws which approach the scope of the Federal Food, Drug, and Cosmetic Act.[18]

[18] These are:

California.—Cal. Health and Safety Code (Deering, 1945), Div. 21, chapters 2 and 3; as to dangerous cosmetics, see Penal Code (Deering, 1941), sec. 382.6.

Connecticut.—Connecticut Food, Drug and Cosmetic Act, Conn. Gen. Stat. (Supp. 1939), sec. 886e, et seq., as amended.

Florida.—Florida Food, Drug and Cosmetic Law, Fla. Stat. (1941), sec. 500.01 et seq., as amended.

Indiana.—Uniform Indiana Food, Drug, and Cosmetic Act, c. 38, Acts of 1939, as amended.

Louisiana.—State Food, Drugs, and Cosmetic Act, Act No. 142, Acts of 1936, as amended.

Missouri.—Act of Aug. 5, 1943 entitled Food and Drugs, secs. 1, 9857–9878A.

Nevada.—Nevada Food, Drug and Cosmetic Act, Nev. Comp. Laws (Supp. 1941), secs. 6206–6206.20.

New Jersey.—N. J. Rev. Stat. (1937), secs. 24:1–1 to 24:6–8, incl., as amended by c. 320, Laws of 1939.

New York.—Baldwin's Consolidated Laws of New York,

Without attempting any detailed discussion of the structure and enforcement of the food and drug laws in the individual states, it is unlikely that any of the individual states has or can expect to have the wide variety of skilled professional personnel whose special talents must be available to deal with the varied problems that arise. Nor can the states be expected to install, equip, and maintain the expensive laboratory facilities necessary to deal with the technical matters involved. It would be an impractical duplication of effort for them to do so, for most drugs in use at the present time are distributed on a multi-state scale. Moreover, variant state requirements would seriously burden the interstate distributor.

It is to be noted that the House Committee Report concerned with overcoming the decision below in the instant case took special cognizance of the effect of the proposed amendments upon federal-state relationships. The report observed not only that the amendments would not disturb

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Agriculture and Markets Law, Article 17, and Education Law, Article 51, as amended.

North Carolina.—North Carolina Food, Drug and Cosmetic Act, N. C. Gen. Stat. (Mickie, et al., 1943), secs. 106–120 to 106–145, incl.

Tennessee.—Tennessee Food, Drug and Cosmetic Act, c. 120, Public Acts, 1941.

Virginia.—Va. Code (Mickie, et al., 1942), secs. 1190 (a)–1190 (p), 1655–1664e, 1698a–1698e.

Washington.—Uniform Washington Food, Drug, and Cosmetic Act, c. 257, Session Laws, 1945.

the preexisting cooperative relationship, but that the proposed amendment already had been approved by the association of state and city food and drug enforcement officers. This portion of the report, which includes the resolution of the local enforcement officers is set forth in the note below.[19]

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[19] H. Rep. No. 807, 80th Cong., 1st Sess., pp. 6–7.

"The enactment of the proposed amendments would not have the effect of excluding State authority in the same field (*Savage* v. *Jones*, 225 U. S. 501). The Food and Drug Administration has worked cooperatively with the States, and the amendments are not intended to disturb that relationship. The needs for consumer protection are such as to require at least the combined efforts of Federal and local authorities.

"Approval of these proposed amendments is expressed in the following resolution adopted unanimously on June 20, 1947, by the Association of Food and Drug Officials, primarily made up of State and city enforcement officers, in its annual conference attended by representatives of 32 State-enforcement organizations:

'RESOLUTION

'In the matter of H. R. 3128 and 3147 and S. 1190 now pending before the Congress. Whereas recent decisions by the Federal courts have seriously restricted the applicability of the Federal Food, Drug, and Cosmetic Act, to interstate shipments of foods, drugs, cosmetics, and therapeutic devices that become adulterated or misbranded after the completion of their interstate transportation, thus drastically curtailing the public protection heretofore afforded under the Federal act; and

'Whereas the States and local authorities have, by common understanding, come to rely in great measure upon the Food and Drug Administration for the inspection and supervision of interstate shipments of foods, drugs, cosmetics, and

The House Committee on Interstate and Foreign Commerce, which has charge of food and drug regulation, has advanced another reason why protection of the product until it reaches the consumer is a proper means of safeguarding interstate commerce. In reporting the proposed

devices to insure that, from these sources, only products that are free from adulteration and misbranding, are delivered to consumers, thus permitting the assignment of the inspectional staffs of State and local agencies to problems more particularly concerned with the commerce of the States; and

'Whereas the activities of the Food and Drug Administration in connection with such goods have been very effective against products which have become contaminated with filth, or otherwise adulterated or misbranded at destination; and

'Whereas the Food and Drug Administration has successfully maintained a program of surveillance over commodities falling within this category without friction or conflict with State law-enforcement agencies exercising like functions with respect to products in the commerce of the State; and

'Whereas the funds and facilities of State and local agencies are generally inadequate to afford satisfactory consumer protection from abuses which occur in this field unless their efforts can be supplemented by enforcement activities under the Federal act; and

'Whereas it has long been the policy and practice of the various State and local agencies and the Food and Drug Administration to plan their respective programs so that the regulatory activities of each will harmonize with and supplement the operations of the other, through the pooling of resources for concerted action where conditions require, or the planning for careful division of work so that personnel can be deployed for maximum coverage to give the consuming public and responsible industry the greatest degree of protection possible within their respective and concurrent jurisdictions: Be it therefore

'*Resolved*, That the Association of Food and Drug Officials of the United States in annual conference assembled in

clarifying amendments to Section 301 (k) (see H. Rep. No. 807, 80th Cong., 1st sess., pp. 19–20, *supra*), the Committee described the effect of sales of misbranded or adulterated products upon the public confidence in the products themselves, and consequently upon the volume of commerce in such products, stating (pp. 4–5):

> It is well known that the defilement of products or deterioration in quality or misrepresentation through relabeling or other abusive acts which occur at any time before articles have been sold to consumers lead to dissatisfaction and lack of confidence

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Carlsbad, N. Mex., express its firm belief in the soundness of the proposal to amend section 304 of the Federal Food, Drug, and Cosmetic Act so as to extend the jurisdiction of the act to products shipped interstate which may become adulterated or misbranded after the interstate transportation has been completed; and that such jurisdiction be extended to the limit of the constitutional authority of the Congress so as to include not only the first sale but subsequent sales as a means of consumer protection and to prevent undue burdens on legitimate interstate commerce; and be it further

'*Resolved*, That it is the belief of this association that the provisions of section 301 (k) should be extended to prohibit acts which result in adulteration as well as misbranding and should be so framed as to be coextensive in all respects with the amended seizure provisions of the Food, Drug, and Cosmetic Act as above proposed; be it further

'*Resolved*, That a copy of this resolution be forwarded by air mail to Hon. Charles A. Wolverton, chairman, Committee on Interstate and Foreign Commerce, House of Representatives; to Hon. Robert Hale, chairman, subcommittee of the House, and to Hon. Wallace H. White, Jr., chairman, Committee on Interstate and Foreign Commerce, United States Senate.'"

which depresses the interstate demand for goods of the same type that are neither adulterated nor misbranded. Testimony before the committee repeatedly referred to that fact. Such abusive acts necessarily and inevitably affect the ability of out-of-State manufacturers to continue marketing their products. If the volume of interstate commerce in foods, drugs, devices, or cosmetics is to be maintained and extended it is necessary that the integrity of the products be preserved, so far as possible, up to the time of purchase by the ultimate consumer. The reputation of any nationally distributed product is impaired and the interstate commerce therein is depressed by adulteration or misbranding while the article is awaiting sale. This is especially true where such adulteration presents a threat to the public health. The misbranding or adulteration of drugs while they are being held for sale which renders their use unsafe or unsuitable because of failure to bear adequate directions for use or warnings against probable misuse, or for any other reason, tends to bring those articles into disrepute and to restrict their proper use. Misbranding which results in ineffectual treatment with a potent drug, such as those of the sulfonamide group, may render the disease organisms immune to the drug. When that resistant strain is spread in the community the sulfonamides are ineffective, even when used by skilled physicians, with the consequence that the

interstate market for those useful drugs is substantially depressed.

Most foods, drugs, devices, and cosmetics are distributed on a multi-State scale. In order to use the facilities of interstate commerce, those articles must be in compliance with the act. Most merchants must obtain any such article, either directly or indirectly, from an out-of-State source or be without it. Public confidence in the effectiveness of interstate regulation inures to the benefit of local distributors through the resulting increase in consumer demand. Having accepted the advantages flowing from interstate regulation, local distributors should not be left free to do acts which deny to consumers the protection Congress intends they should have, and which, in practical effect, appropriate the channels of interstate commerce as an instrumentality for working harm upon consumers.

We submit that the facts set forth in this passage from the Committee Report afford an additional reason for holding that the Congress may legitimately exercise its commerce power so as to require correct labeling up to the point of sale to the ultimate consumer.

The view which we urge does not impose hardship on the local retailer. Specifically, with respect to respondent, the container of sulfathiazole which he purchased from the jobber had a proper interstate label, and this label, in addition to bearing a warning concerning "severe toxic reac-

tions" which the drug might cause, plainly informed respondent: "Caution—to be used only by or on the prescription of a physician." See *supra*, p. 8. Respondent need only have heeded the cautionary instructions and dispensed the medicine pursuant to a physician's prescription; he would have had adequate directions for use as prescribed by the physician and these would have been reflected on the prescription label which is placed on such products. It is solely because respondent flaunted the warning and cautionary instructions placed on the product by the producer for the benefit of the consumer that he finds himself in his present predicament.

It is true that if a distributor or dealer undertakes to sell the interstate article in smaller quantities than the original package the smaller packages, too, must be properly labeled. But this is not a great burden. In most instances the manufacturer not only labels the interstate container, but also the individual packages placed therein, as is the case of canned goods. In these circumstances the local seller is required only to leave the label alone. Where this is not the situation, the choice is between placing the responsibility on the retailer to affix appropriate labels on the packages which he holds for sale, as under the Wool Products Labeling Act where the wool has been manufactured into clothing (see *supra*, p. 43), or to defeat the congressional purpose by

permitting the retailer to separate the articles from their interstate label and to hold them for sale either without labeling or with improper labeling. The danger to purchasers of improperly labeled drugs clearly outweighs any inconvenience to the seller from having to copy the label.

CONCLUSION

For the reasons stated we respectfully submit that the judgment of the circuit court of appeals should be reversed.

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NOVEMBER 1947.

U. S. GOVERNMENT PRINTING OFFICE: 1947